In addition, the advertisement fails to achieve fair balance in that the advertisement failed to give the reader a more properly balanced view of this new drug by not including the summary view, expressed by the moderator at the end of the symposium, that Indocin's use ". . . warrants a lot more study and observation. Its long-term effect in rheumatoid arthritis is still unknown. . . ."

B. The article is misbranded within the meaning of 502(n) in that the journal advertising failed to present information concerning those side effects and contraindications that are pertinent with respect to the uses recommended or suggested in the advertisement as required by regulation 1.105(f)(1) in that the following important information has been omitted:

1. The warning that "as with other anti-inflammatory agents, Indocin may mask the signs and symptoms of peptic ulcer."

2. The warning that "indomethacin itself may cause peptic ulceration or irritation of the gastrointestinal tract."

3. The contraindication that "indomethacin is contraindicated in asprin-sensitive asthmatics."

4. The precaution that "indomethacin should be used with caution if there is a history of ulcer, gastritis, regional ileitis, or ulcerative colitis, because of its potential for causing gastrointestinal bleeding."

5. The precaution that "It [indomethacin] may cause simple or multiple ulceration of the stomach, duodenum, or small intestine."

6. The precaution that "a possible potentiation of the ulcerogenic effect of these drugs cannot be ruled out at present."

7. The side effect information concerning "ulceration of the esophagus, convulsions, nausea, anorexia, vomiting, epigastric distress, abdominal pain, diarrhea, gastritis, jaundice, hepatitis, elevation of blood pressure, hematuria, angioneurotic edema, angiitis, rashes, loss of hair, acute respiratory distress including dyspnea and asthma, purpura, thrombocytopenia, agranulocytosis hearing disturbances, orbital or pariorbital pain, vaginal bleeding, hyperglycemia, and glycesuria."

C. The article is misbranded within the meaning of 502(n) in that the journal advertisement does not prominently display the name of at least one specific dosage form and quantitative ingredient information in direct conjunction with such display as required by regulation 1.105(d)(2).

FEBRUARY 14, 1968.

From: R110.
To: R100—Mr. Barnard.
Subject: 126–350B Indocin—Merck Sharp & Dohme.

SUMMARY

Attached is Philadelphia District's S&R of 2–6–68, renewing their recommendation of prosecution in this advertising case.

Merck's response to the Notice of Hearing is a written response by the Law firm of Drinker Biddle & Reath. The response presents legal, administrative and medical arguments against forwarding.

This matter was the subject of a conference between BRC, Med & GC last October. (See Memo of Conf. 10–16–67, cy. attached.)

Your guidance in this matter will be appreciated.

Bureau of Medicine has not reviewed the Merck's response to this most recent citation.

D. W. JOHNSON.

PHILADELPHIA DISTRICT,
February 6, 1968.

SUMMARY AND RECOMMENDATION

SUPPLEMENTAL

Sample number, 126–350 B; product, Indocin Capsules, 25 Mg.;
Date shipped (On or about), 11–7–66; Carrier, Parcel Post; Seizure, None.
(This hearing involved additional citation on the sample which was the subject of Summary and Recommendation submitted on January 26, 1967.)